UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA	:	
- v. -	:	S6 20 Cr. 160 (MKV)
SETH FISHMAN, and LISA GIANNELLI,	:	
Defendants.	:	

THE GOVERNMENT'S RESPONSE IN OPPOSITION
TO THE DEFENDANT'S MOTIONS *IN LIMINE*

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PRELIMINARY STATEMENT

The Government respectfully submits this memorandum of law in opposition to Seth Fishman's and Lisa Giannelli's motions *in limine*. (hereinafter "Def. MIL" (*See* Dkt. Nos. 571, 574)).[1] The defendants' motion moves to preclude: (i) the introduction of, and any cross-examination regarding, the Delaware State Division of Professional Regulation's investigation into the defendants following the death of a horse that was administered a substance sold by Giannelli; (ii) the introduction of what the defendants incorrectly refer to as "other crimes" evidence, namely, Seth Fishman's manufacture and export of products to the United Arab Emirates, a foreign purchaser's outreach to Seth Fishman to create a custom-made "female Viagra" and false representations made by this same purchaser in the course of litigating a motion for the return of property pursuant to Federal Rule of Criminal Procedure 41; (iii) the introduction of Seth Fishman's statements made under the protections of proffer agreements extended by the Eastern District of New York (on one occasion) and the Southern District of New York (on subsequent occasions following Fishman's initial, unprotected statement the day of his arrest); and (iv) the introduction of testimony by three of the Government's expert witnesses. For the reasons set forth below, the defendants' motions should be denied in their entirety.

ARGUMENT

I. Evidence of the Delaware State Division of Professional Regulation Investigation Into Fishman and Giannelli Is Admissible As Direct Proof of the Charged Offense

For the reasons set forth in the Government's motions *in limine*, ECF No. 572, evidence of the 2011 investigation by the Delaware State Division of Professional Regulation, which is

[1] The defendants' separately-filed motions *in limine* contain identical arguments; the Government therefore files this opposition in brief in response to both papers.

responsible for regulating licensed professionals (such as veterinarians) in Delaware, is admissible as direct evidence that the defendants: (1) distributed adulterated and misbranded drugs insofar as Giannelli sold an injectable drug that required a prescription, without any valid prescription; (2) the defendants were on notice as of at least the time of that investigation of various facts that bear upon their state of mind and fraudulent intent[2]; (3) when under investigation, both Fishman and Giannelli – the latter a Delaware resident – lied about the scope of Giannelli's duties when working under Seth Fishman, which bears directly upon the pair's intent to defraud or mislead a state regulatory agency.

The defendants' motion misses entirely the import of that investigation and the permissible purposes for which it is offered as direct proof of the charged offenses. The Government does not intend to establish that a drug distributed by Fishman and Giannelli caused the death of a horse, as suggested by the defendants in their motion, *See* Def. MIL at 7. There is therefore no danger of engaging in a "mini-trial" regarding whether that particular horse died because the administered drug was toxic, because the administering layperson was unqualified to administer a potent injectable prescription drug, or because of some other cause. *Id.* The Government will not offer this evidence to litigate that horse's cause of death, but to demonstrate, as stated above and in the Government's motions *in limine*: the fact of a state regulatory agency's oversight of Fishman and Giannelli; that Fishman and Giannelli were placed on notice as to certain factors relevant to their

[2] As outlined in the Government's motions *in limine*, in receiving and responding to the Complaint filed against them, both defendants were indisputably on notice as to several factors that bear upon their culpable state of mind, including: that veterinarians must establish a valid veterinarian-client-patient relationship ("VCPR") before dispensing prescription drugs; that non-veterinarians may not dispense prescription drugs; that it is illegal to distribute non-FDA-approved prescription drugs, particularly in the absence of any VCPR; that the foregoing could run afoul of federal law; and that the foregoing was of particular concern to state drug regulators, including the Delaware authorities investigating Fishman and Giannelli.

state of mind with respect to the charged offense; and, further, to demonstrate that their false statements to the state investigating agency evinced both their consciousness of guilt and their intent to mislead and defraud a state regulator. As such, proof of Fishman and Giannelli's interactions with this agency are highly relevant to establishing their state of mind at the time of the investigation and thereafter. There is consequently no undue prejudice under Rule 403 to presenting evidence regarding this investigation in the Government's case-in-chief, and any prejudice does not outweigh the probative value of this evidence.

The defendants argue, in the alternative, that they "should be permitted to elicit the fact that the Complaint in this case was ultimately dismissed." Def. MIL at 7. After the Delaware investigation (which, as noted, included demonstrably false, sworn statements by both Fishman and Giannelli) was referred to the Attorney General's office for prosecution, that separate office declined to criminally charge the defendants and dismissed the case in a one-sentence letter stating that the office believed it possessed insufficient evidence to proceed. *See* Exhibit A.[3] That decision is both wholly irrelevant and constitutes hearsay for which no exception exists under the Federal Rules of Evidence. *Cf. United States v. Viserto*, 596 F.2d 531, 537 (2d Cir. 1979) ("[A] judgment of acquittal is not usually admissible to rebut inferences that may be drawn from the evidence that was admitted [at trial]. Not only does the inference appellants suggest not flow from the judgment of acquittal of [defendant], but also a judgment of acquittal is hearsay. The Federal Rules of Evidence except from the operation of the hearsay rule only judgments of conviction, Rule 803(22), not judgments of acquittal."); *see also United States v. Delgado*, 903 F.2d 1495, 1499 (11th Cir. 1990) ("There are many factors that influence the government's decision not to prosecute

[3] Given the sensitivity of the information contained within Exhibits A through H, the Government respectfully requests that the exhibits be maintained under seal.

a defendant on certain charges. . . . Certainly, we cannot attribute the government's decision not to prosecute to an independent determination that the defendant is not guilty.").[4]

II. The "Other Crimes" Evidence The Defendants Contest Are Direct Proof of the Charged Conspiracy And Further Bear Upon Seth Fishman's State of Mind

A. The Manufacture and Export of Drugs To the United Arab Emirates Is Direct Proof of the Charged Conspiracy

As the Government argued in its motions *in limine*, Seth Fishman's shipment of adulterated and misbranded performance-enhancing drugs to other countries—including the United Arab Emirates[5]—were encompassed within Fishman's overall illegal drug business and are therefore admissible as direct evidence of the charged offenses. Moreover, and in light of the arguments

[4] Admission of the Delaware Attorney General's declination would, moreover, invite a sideshow regarding the *opposite* conclusion of the relevant regulator and investigative entity. Indeed, notwithstanding the State Attorney General's declination, Delaware State's July 11, 2012 Investigative Report referring the case to the Delaware State Attorney General's Office for prosecution firmly concluded that "Dr. Fishman *is in direct violation of*" several Delaware State provisions: (1) Title 11, Del. Crim. Code, Section 1325, which requires veterinarians to provide proper veterinary care and to "prevent unnecessary or unjustifiable physical pain or suffering by the animal," and further prohibits cruelty to animals; (2) Title 28, Del. Code, Section 705 which prohibits "interfering or attempting to interfere with, tampering, injuring or destroying by the use of any narcotic, drug, stimulant, appliance or by any other means any horse that is to participate in a running race or a harness race"; (3) Title 24, Del. Code, Section 3300, setting forth grounds for unprofessional conduct by veterinarians, which includes "[a]llowing support personnel to perform" certain forbidden acts, and "[i]mproper labeling of prescription drugs"; and (4) Title 24, Del. Code, Section 3316, which prohibits "[i]llegally, incompetently or negligently practice[ing] veterinary medicine," or cruelty to animals. *See* Exhibit B. The Government is not seeking to admit this conclusion of guilt, but assuming that the defendants were allowed under the Rules of Evidence to offer evidence regarding the State Attorney General's declination (and they are not), that evidence would be fairly met with an accurate recitation of the manner in which the case was first determined to be a violation of state law, and subsequently declined by a separate, prosecutorial office without discussion of any of the underlying proof, or any apparent awareness of the defendants' false statements.

[5] The defense motion moves solely to preclude evidence regarding Fishman's overseas shipments to the United Arab Emirates, presumably conceding that his foreign sales to other countries are admissible as direct proof of the charged offense.

raised in Fishman's motion, the defense should be precluded from arguing that the FDCA's "export exemption" applies to Fishman's foreign sales in the absence of any evidentiary foundation to argue this affirmative defense. As an initial matter, Fishman's exported drugs were adulterated and misbranded under the FDCA notwithstanding the fact that he purports to have sold some quantity to foreign purchasers, and the Indictment specifically charges Fishman's overseas shipments of drugs as part of his conspiracy. *See* S6 Indictment ¶ 8 (describing Seth Fishman's conspiracy as involving the manufacture, shipment, marketing, and distribution of adulterated and misbranded PEDs "to various racehorse trainers across the country and internationally").[6] Foreign sales of Fishman's drugs are thus squarely within the scope of the offense conduct charged in the Indictment. Fishman used the same facilities, employees, and co-defendants to manufacture and label drugs for both overseas and domestic customers; distributed (and offered for sale) the same products to domestic and foreign customers; promoted the drugs using the same promise of "untestability"; and offered excess inventory from large orders of drugs manufactured for foreign customers to domestic customers. In short, Fishman's foreign sales are not "other crimes" evidence as characterized by the defendants, these are direct evidence of the charged crimes.

The defendants argue without support or elaboration that any foreign sales fell under the FDCA's so-called "export exemption" set forth in Section 801(e) of the FDCA. Def. MIL at 5. Critically, that exemption (which constitutes an affirmative defense on which the defendants will bear the burden of proof and persuasion) applies *only* if, among other things, the drugs shipped overseas "accord[] to the specifications of the foreign purchaser," are "not in conflict with the laws of the country to which it is intended for export," are properly labeled as drugs "intended for

[6] Consequently, the Government has already "describe[d]" in what manner "the products exported for use by the Presidential Affairs Department were 'illegal.'" Def. MIL at 5.

export," and are "not sold or offered for sale in domestic commerce." 21 U.S.C. § 381(e). The defendant has the burden of establishing that this "narrow[]" exemption applies to his foreign sales, which it does not. *See United States v. Kanasco, Ltd.*, 123 F.3d 209, 211 (4th Cir. 1997) ("The burden of pleading and proving the applicability of § 381(e)(1) is on [the defendant]—the party that seeks the benefit of the exemption," and noting that the export exemption must be construed "narrowly" (citing cases)); *see also United States v. Endotec, Inc.*, 563 F.3d 1187, 1195 (11th Cir. 2009) (holding that manufacturer bore burden of demonstrating that the separate "custom device" exception applied, and collecting cases); *cf. United States v. Mayo*, 705 F.2d 62, 75 (2d Cir. 1983) ("The Supreme Court in *Patterson v. New York*, described an affirmative defense as one that 'does not serve to negative any facts of the crime.'" (quoting *Patterson*, 432 U.S. 197, 206-207 (1977))).

Fishman attempts to turn this exemption on its head by claiming that "the Government should be required to set forth, in detail, the manner in which these shipments allegedly ran afoul of the export exemption." Def. MIL at 5. It is not the Government's burden to prove that Fishman's shipments comported with the narrow exception that would permit otherwise misbranded and adulterated drugs to be sent exclusively in foreign commerce to a specific purchaser and subject to specific formulations. The onus on invoking the exemption to a generally applicable statute rests with the defendant who seeks the benefit of an affirmative defense. Despite self-servingly reciting this exemption in multiple filings, Fishman has made no predicate factual showing that his overseas exports were exempted from the FDCA, nor can he, given that the same drugs he shipped overseas were sold or offered for sale domestically and designed *not* to the specifications of a foreign purchaser, but to Fishman's own specifications, which were designed to evade drug tests domestically and globally.

Fishman incorrectly presumes that the solution is hemming the presentation of relevant evidence of the defendant's shipments to the United Arab Emirates. Far from it. The defense should be precluded from invoking—through evidence, argument, or questioning—this affirmative defense, for which there is no good faith basis to believe that admissible evidence in support will be tendered by the defense. *See United States v. Villegas*, 899 F.2d 1324, 1343 (2d Cir. 1990) (where evidence of coercion is "insufficient as a matter of law" to prove the affirmative defense of duress, "no proper interest of the defendant would be served by permitting his legally insufficient evidence to be aired at trial, and interests of judicial economy suggest that the jury should not be burdened with the matter. . . . Accordingly, the district court . . . properly ruled prior to trial on whether or not the defendants' proposed duress defenses could be deemed sufficient as a matter of law, and whether, therefore, they should be allowed to present such defenses to the jury."); *see also United States v. Lorenzo*, 52 F. App'x 553, 554 (2d Cir. 2002) (where defendant "failed to proffer any facts to support her claim that she was acting under duress when she committed the frauds in question . . . . the district court was correct to preclude argument regarding duress and well within its discretion to exclude [defendant's] proposed expert testimony"); *United States v. Adelekan*, No. 19 CR. 291 (LAP), 2021 WL 4847894, at *7 (S.D.N.Y. Oct. 18, 2021) (granting Government's motion *in limine* to preclude defendants from offering evidence or argument at trial in support of affirmative duress defense because defendants "either disclaimed such a defense or made no attempt to make a showing as to any of these elements"). Examining in front of the jury "the particulars of the export exemption," Def. MIL at 5, when there is no foundation to do so, would result in the presentation of concepts that are irrelevant, unduly prejudicial, confusing, and a needless waste of the jury's time. *See* Fed. R. Evid. 403.

Accordingly, the Government should be permitted to present relevant evidence of the defendant's foreign sales of adulterated and misbranded drugs, all of which are direct evidence of the charged crime and all of which further reflect Fishman's ill intent as to even his domestic clients. Moreover, Fishman should be barred from relying on the "export exemption" as an affirmative defense, the elements of which he has not and cannot marshal.

B. Evidence of A Foreign Purchaser's Request that Seth Fishman Create and Ship "Female Viagra" Is Fairly Admissible In Response to Certain Anticipated Defense Arguments

On or about November 17, 2019, the Government provided notice to the defendants that it may seek to introduce evidence that a particular foreign purchaser "ha[d] solicited Seth Fishman to distribute performance enhancing drugs, and to create and distribute other illegal drugs," such as a February 2018 request by this purchaser to Fishman "to create and provide a 'Viagra drink' and 'Viagra for ladies.' " *See* Def. MIL Exhibit B. The Government does not intend to introduce in its case-in-chief evidence that Seth Fishman was asked to create such a drink and that he, in fact, attempted to do so. The Government, however, reserves the right to offer it in any rebuttal case, if necessary to respond to certain defense arguments. For example, should the defendants seek to argue that Fishman lacked the capability, willingness, or technical knowledge to manufacture novel drugs, evidence that Seth Fishman was asked to, and attempted to, manufacture "Viagra for ladies" is fairly admissible to rebut that notion. Likewise, should the defense argue—as Fishman and his foreign purchaser did, falsely, in the course of their failed Rule 41 litigation—that Seth Fishman merely sold therapeutic camel medications to that particular foreign purchaser within his capacity as a veterinarian, evidence that Fishman was asked by this same agency to create a customized, adulterated and misbranded drug intended for human use is powerful evidence

that Fishman was not treating patients as a licensed veterinarian, but was manufacturing customized drugs at the behest of unscrupulous purchasers.

The defendant claims in his papers that "[t]here is no indication that the defendant subsequently shipped a substance intended for this use," and that discussions regarding this drug were merely a joke. Def. MIL at 6. Not so. The defendant's calls and text messages demonstrate that he took this request seriously, asking several follow-up questions and requesting particulars, and appeared to have worked with Jordan Fishman to create such a drug, as requested. On or about February 24, 2018, Fishman's foreign purchaser, claiming to act on behalf of a purported agency known as "Presidential Camels," sent Fishman a message: "[Individual] want that Viagra drinks as soon as possible," elaborating, when asked, "The one you put in juice." Exhibit C. Fishman responded, "I need picture and specifics." *Id.* The purchaser wrote back the next day, "This Viagra for ladies what [Individual] want" and subsequently sent a video file that depicts, in substance, an individual (who appears to be filming the video on a camera phone) grinding a pink pill into a powder; a woman drinking a can of Red Bull and leaving the room; that same individual pouring the pink powder into the woman's drink; and the woman reentering the room and drinking from the can of Red Bull, apparently unsuspecting that the drink had been spiked with a drug. The first two seconds of the video contain the text "Ladies and Gentlemen" and "Female Viagra." Exhibit D. Fishman wrote back later that day, "That's a video. There are illegal date rape drugs that don't even work like the video. Please I need a clear email of exactly what he is looking for." Exhibit C. The purchaser responded, "Simply Seth he want Viagra for ladies can be added in juice for example It doesn't matter the same as in the video." *Id.* Fishman wrote back on March 3, 2018, "I can make BI-AGRA. Female viagra so strong it makes the woman bisexual. Have 2 girls that will make short film similar to that one you sent. Need to know how many bottles he wants. If he

wants large number we can blister pack tablets and design box. I assume you want all natural and not pharmaceutical. I will start the project after I am paid for last years services." *Id.*

Over one year later, Seth Fishman and Jordan Fishman exchanged text messages regarding this project; on or about August 5, 2019, Jordan Fishman wrote, in part, "I was about to write you, they are done and fine. The only issue that was a problem is that the Viagra is only soluble at 4.1 mg per mil. This forced me to take some of the juice and dissolve the Viagra and then put about 7 ml in each bottle first as we discussed and then 33 ml pumped with all of the other ingredients. It just took a long time . . . We're sending about 50 extra of both these special silver so a total of approximately 160 odd bottles and we did approximately 660 bottles of the fold. The pallet is already scheduled to be picked up[.]" Exhibit E at 2. Seth Fishman wrote in response, "Ok what is charge per bottle total," and the two discussed pricing regarding the shipments of juice containing Viagra. Approximately ten weeks later, on October 20, 2019, while Seth Fishman was in the United Arab Emirates days before he flew back to the United States and was arrested, Fishman wrote to Jordan Fishman, "We need to finish the injectable Viagra and Cialis. *Presidential* A today asked about it. Did you get the PEG or are we just going to use PG. also can try them in pure DMSO." Exhibit C at 1 (emphasis added).

Accordingly, Seth Fishman's willingness to produce "Female Viagra" has ample factual support, and is fairly introduced to rebut certain defense arguments that are contradicted by this evidence.

C. The Government Should Likewise Be Permitted To Introduce The Filings In The Rule 41 Litigation To Fairly Respond to Certain Defense Arguments

On or about March 20, 2020, a Motion and Memorandum of Law for Return of Drugs was filed in the United States District Court for the Southern District of Florida by a party referring to

itself as "Presidential Affairs Department: Sector of Scientific Centers & Presidential Camel Department, Dubai Equine, and Dubai Camels" ("the Petitioners")[7] pursuant to Rule 41(g) of the Federal Rules of Criminal Procedure, seeking to have law enforcement turn over to the Petitioners various items, including adulterated and misbranded drugs, seized from Seth Fishman's residence, office space, and storage locker (the "Petition"). The Petition argued that the items seized by law enforcement in fact belonged to the Petitioners and had been seized in violation of the Fourth Amendment. The Petition further argued that the items were not contraband, but rather drugs intended for export to the United Arab Emirates for the purpose of camel breeding.[8] The Government opposed the Petition.[9] The Petitioners filed a reply, to which they attached a

[7] The foreign purchaser referenced above purported to be a representative of one of the Petitioners in the course of that litigation.

[8] The papers filed by the petitioners in that action provided shifting explanations regarding the intended uses of those drugs as the provided evidence contradicting the Petitioners' baseless claims.

[9] In his motion *in limine*, Fishman asserts that "the Government did not allege that statements contained in Petitioner's Rule 41(g) application were false." Def. MIL at 7. In fact, the Government repeatedly used the word "false" in characterizing the Petitioners' statements. *See e.g.*, Government Surreply at 1 ("Nevertheless, the Court need not address the Petitioners' ***false*** claims because Petitioners have failed to articulate the facts necessary to merit a Rule 41(g) hearing, let alone to prevail on their Motion.") (emphasis added); *id.* at 6 ("Much of Petitioners' claims regarding the use of the Seized Property in the Navarro case, and their claims that the Seized Property are not contraband, are premised on ***false representations*** that the Seized Property has been custom-made for Petitioners' camels, whereas Seth Fishman has been indicted of a conspiracy pertaining to manufacturing and distributing drugs to dope racehorses.") (emphasis added); *id.* at 12 (Even accepting for the sake of argument Petitioners' ***(false)*** premise that these drugs were intended for breeding, treating, and vaccinating camels, ….") (emphasis added). The Government also characterized the Petitioners' claims at various points as "spurious," "misleading" and even "astoundingly misleading." *See e.g.*, Government Response in Opposition at 12 ("The Petitioners' claimed need for the Seized Property in anticipation of the camel breeding season is spurious given that the alleged breeding season has already come and gone…with no attempt by the Petitioners to contact the Government to seek the return of the Seized Property."); Government Surreply at 4 ("In short, the invoices, even if authentic, suggest at most that Petitioners' original submission misleadingly claimed ownership of property that was not, in fact,

declaration from Fishman's then-attorney, Andrew Feldman, Esq., which represented to the Court, in substance and in part: (1) several instances in which Fishman and/or his counsel had previously informed the agents and/or prosecutors that seized products were intended for export or were products for camels; and (2) that counsel's review of draft transcripts of intercepted phone calls between Seth Fishman and others showed "that, during some of the intercepted calls, Mr. Fishman was speaking to UAE clients or international clients." Feldman Decl. ISO Petitioners' Pet. for Return of Property. The declaration omitted mention of the scores of intercepted phone calls and text messages between Fishman and domestic clients, those between Fishman and overseas clients regarding doping horses, and those involving overseas clients *other than* Petitioners (for example, purchasers in Canada, or private, non-governmental purchasers in the U.A.E.). The declaration further omitted reference to the fact that the intercepted communications overwhelmingly referred to doping horses for the purpose of succeeding in competitive racing, rather than for the purpose of improving "breeding" or treatment of exotic diseases. On or about May 1, 2020, the Petition was denied.

Later that same day, Fishman filed a Motion to Intervene and to Request Consideration of the Order Denying Petitioners' Motion to Return Property. His motion to intervene regurgitated many of the same arguments made by the Petitioners, namely, that the Government seized the items in violation of the Fourth Amendment, and that the items seized were camel products intended for sale in the UAE. Neither Petitioners nor Fishman produced documentation

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intended for sale to the entities reflected in the Petitioners' attachments, and that Fishman's possession of drugs cannot be equated with ownership by a particular customer."); *id.* at 6 ("Petitioners' claims that the Seized Property consist of drugs custom-made for breeding, vaccinating, and otherwise treating 'common diseases' in Petitioners' camels is astoundingly misleading…and is undermined by arguments in Petitioners' Motion and information obtained by the Government in the course of its investigation.").

establishing that the seized items were intended for export, or that they satisfied the requirements of the FDCA's "export exemption."

The Government does not intend to introduce in its case-in-chief evidence that: (1) Fishman was involved in the decision of the Petitioners to file a motion seeking to have law enforcement return the seized items (which he was); (2) Fishman's then-attorney filed a declaration on Fishman's behalf in efforts to compel the Government to forward seized evidence to Fishman's customers abroad; or (3) Fishman sought to intervene and move for reconsideration by repeating the same deeply misleading arguments advanced previously by Petitioners. However, the Government reserves the right to refer to such evidence during questioning, or introduce it in any rebuttal case, if necessary to respond to certain defense arguments. For example, should Fishman offer evidence that he compounded drugs solely for sale to foreign customers under the "export exemption" to the FDCA, evidence that Fishman sold the same drugs domestically as he did overseas is fairly admissible in response, particularly where Fishman's main foreign customer was unable to substantiate through competent records that it had, in fact, purchased the items seized at Fishman's warehouse. Further, should Fishman argue that he has "nothing to hide" or has otherwise been an "open book" regarding his drug manufacturing activities, the false statements Fishman made and adopted in his motion to intervene, and those made on his behalf, are likewise admissible to demonstrate Fishman's consciousness of guilt, and to undermine the false notion that he sought to comply with the letter of the law following his arrest. Likewise, should the defense advance any argument that Fishman manufactured drugs for purposes *other than* export to the U.A.E. for use on camels, the Rule 41 action is also admissible to demonstrate Fishman's and the Petitioners' roving explanations regarding the intended uses of his drugs.

III. The Government Should Be Permitted to Introduce Seth Fishman's Proffer-Protected Statements If Fishman Opens the Door To His Statements

As argued in the Government's motion *in limine*, the Government will only seek to admit any statements made by the defendant pursuant to the limited protections of a proffer agreement if Seth Fishman "opens the door" to such statements. *See* Gov't MIL at 15-20. Any such proffer-protected statements and the governing proffer agreements in the *Brooks* matter[10] and in this matter were produced to Fishman over one year ago and Giannelli over six months ago; the defense consequently has "prior notice of the content of the alleged statement[s]," Def. MIL at 7, the Government may seek to admit at any trial, assuming Fishman—through testimony, evidence, or argument—opens the door to such statements. As stated in the Government's prior submission, this issue is not yet ripe as Fishman has yet to open the door to any such statements. The Government anticipates providing prior notice before introducing any proffer-protected statements; as such, the defense's argument on this score is moot.

IV. The Government's Expert and Lay Witnesses Should Not Be Precluded From Testifying

A. Dr. Jean Bowman, DVM

As an initial matter, the defendants concede that Dr. Bowman is qualified to opine regarding the: (1) "requisite information and data that must be submitted to the FDA in a new

[10] The defense and the Government are in agreement that the proffer agreement extended in the *Brooks* trial encompassed only "the Government's initial interview with Dr. Fishman," and not subsequent interviews that took place without the benefit of a proffer agreement, and without the presence of counsel. *See* Def. MIL at 7. The Government has produced all such reports of interviews between Fishman and the trial team litigating the *Brooks* case, with the understanding that only the statements made at the initial meeting are subject to any limitations as to their use at trial. Similarly, Fishman's statements during a voluntary interview the day of his arrest in this matter were not subject to any protections; consequently, the Government may also present evidence of those statements at trial without restriction.

animal drug application," and (2) database searches revealing no approvals, conditional approvals, investigations, or index listings for the defendant's equine products. Def. MIL at 10. The defense, however, takes exception to Dr. Bowman's expert testimony in two respects.

First, the defendants seek to preclude Dr. Bowman from opining as to the "safety and efficacy" of Fishman's drugs, claiming that this issue is "not relevant to the issues at trial" and that the defendants are not charged with manufacturing and distributing "unsafe" animal drugs. The defendants' arguments completely miss the mark. The statutory definition of a "new animal drug" under the FDCA includes a drug "the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of animal drugs, as *safe and effective for use* under the conditions prescribed, recommended, or suggested in the labeling thereof[.]" 21 U.S.C. § 321(v)(1). Moreover, the defendants *have* been charged with distributing "unsafe" drugs: Fishman has been charged with distributing drugs that are *adulterated* and misbranded. A drug is deemed adulterated "if it is a new animal drug which is unsafe" within the meaning of the FDCA, 21 U.S.C. § 351(a)(5), and a drug is considered "unsafe" if it is a new animal drug, *i.e.*, a drug that does not have a "general reputation in the scientific community" as "safe and effective for its intended uses," *see United States v. Undetermined Quantities of Various Articles of Drug . . . Equidantin Nitrofurantoin Suspension ...*, 675 F.2d 994, 999–1000 (8th Cir. 1982) (citation and internal quotation marks omitted). Fishman's new animal drugs, by definition, are "unsafe."

In order for the Government to establish an essential element of one component of the offense—that Fishman's drugs were adulterated because they were new animal drugs for which no approval existed—the Government must present proof that at least certain of those drugs are new animal drugs that are not considered among qualified experts in the scientific community to

be "safe and effective" for use as contemplated under the FDCA. The defendants' arguments to the contrary are meritless.

Dr. Bowman's (undisputed) testimony regarding the "requisite information and data that must be submitted to the FDA in a new animal drug application" will necessarily include discussion of the FDA's standards for evaluating the safety and efficacy of a drug, and the application of this standard to several of Fishman's unapproved drugs, as identified in the Government's expert notice letter. *See* Def. MIL Exhibit E. This testimony should come as no surprise given the statutory definition of a "new animal drug"; a fundamental cornerstone of the FDA's drug approval process is ensuring that a new drug is safe and effective for its intended use. Specifically, in reviewing applications for new animal drugs, the FDA evaluates whether the drug in question performs the function it is intended to perform at the recommended dosage, pursuant to the recommended directions for use, and the side-effects are not so harmful as to outweigh the drug's intended benefits.[11] Discussion of whether Seth Fishman's drugs meet this standard is consequently relevant to establishing an essential element of one object of the charged offenses, namely, that his drugs are not generally recognized as "safe and effective" for their intended use. Expert testimony is appropriately admitted for this purpose. *See, e.g.*, *United States v. Writers & Rsch., Inc.*, 113 F.3d 8, 10–11 (2d Cir. 1997) (noting that the government "offered expert testimony that [the drug at issue] has not been clinically established

[11] For example, a new drug purporting to be an analgesic, but which did not relieve pain, would not be effective, and thus may not receive approval from the FDA. Similarly, an effective analgesic drug that relieved minor aches and pains, but which also caused permanent blindness, may be effective at treating minor pain, but would not be considered safe due to its side effects, and may consequently not receive approval from the FDA. The FDA's regulatory oversight of new animal drug applications involves balancing the safety and efficacy of a given drug, whereas Fishman's secretive manufacturing process risked the distribution of drugs that were unsafe, ineffective, or both.

as safe and effective for use in the treatment of human diseases nor is the drug generally recognized as safe and effective for that purpose among qualified experts."); *cf. United States v. Premo Pharm. Lab'ys, Inc.*, 511 F. Supp. 958, 973–74 (D.N.J. 1981) (civil case in which district court issued a preliminary injunction in reliance on testimony from six expert witnesses opining that the products in question "are not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof.").[12]

Second, and relatedly, the defense seeks to "preclude testimony suggesting that the purpose of the statutory scheme is to ensure the wellbeing of the racehorses." Def. MIL at 11. That issue is moot insofar as the Government does not intend to elicit from Dr. Bowman testimony regarding the public policy reasons underpinning Congress' passage of the FDCA. The Government should be permitted, however, to question Dr. Bowman generally regarding her work at the FDA's Center for Veterinary Medicine ("FDA-CVM") and the mission and/or purpose of that agency, which encompasses protection of the public, including animals. Indeed, the defendants have previously argued that such a mission is critical to a particular agency being cognizable under the FDCA as a "victim" of the defendants' intent to defraud or mislead. *See generally*, Fishman and Giannelli's Mot. to Dismiss at 33-37 (arguing repeatedly that only

[12] The defendants misconstrue Dr. Bowman's testimony as equivalent to expert testimony regarding the dangers of heroin, cocaine, or fentanyl. Dr. Bowman's anticipated opinions are more akin to a controlled substance analyst rendering the expert opinion that a particular powder is in fact a controlled substance, *i.e.*, heroin, cocaine, or fentanyl. It is axiomatic that such expert testimony is admissible to prove a necessary element of a narcotics offense under the Controlled Substances Act. Here, Dr. Bowman's testimony is offered to establish that certain of the drugs Fishman and Giannelli distributed were unsafe insofar as they were not generally recognized as safe and effective, and were consequently adulterated. Such testimony is not superfluous or gratuitous; it is probative of an element of the charged crime.

agencies involved in consumer protection are cognizable victims of FDCA violations, and specifically contesting whether state racing commissions qualify as victims given that "the core legislative purpose of these state instrumentalities" is not "concern[] with consumer protection." (ECF No. 327)).

Dr. Bowman is certainly qualified to opine as to the goals and purpose of her employment generally. Further, as explained above, Dr. Bowman may permissibly explain various aspects of the FDA's regulatory role, particularly with respect to the approval of new animal drugs, which will necessary involve testimony regarding the FDA's review of the "safety" of a new drug in the new animal drug approval ("NADA") process. Such testimony involves concepts that are foundational to the FDA's NADA process, which the defendants do not seek to preclude. For example, Dr. Bowman is anticipated to testify that during the NADA process, the FDA reviews whether a drug manufacturer employs good manufacturing practices, that component chemicals in a drug are sourced from registered suppliers, and that the drug has adequate directions for use, all with the aim of ensuring the safety of a drug. Dr. Bowman is also anticipated to testify regarding the factors the FDA considers when determining whether a drug may be marketed and sold as a prescription or over-the-counter drug, including the riskiness of the method of administration. Thus, Dr. Bowman may fairly opine as to these issues, given that they form the bases for the FDA's evaluation of a new animal drug.

Consequently, there is no basis to limit Dr. Bowman's anticipated testimony.

B. Dr. Diana Link, DVM

The Government notified defense counsel, out of an abundance of caution, that Diana Link, a veterinarian and employee of the FDA-CVM, would testify at trial given her presence during a search of Fishman's office space. As such, Dr. Link will be able to authenticate (as a lay

witness) photographs of the search and describer her general observations of the office, and will be able to contrast her observations with her prior personal observations of practicing veterinary clinics. The Government does not intend to qualify Dr. Link as an expert witness and seeks to elicit only her firsthand observations as a fact witness. Dr. Link, as with the other proposed experts, is not anticipated to testify regarding the ultimate issue of whether Seth Fishman's drugs are adulterated or misbranded, which appears to be the only basis for the defense's objection to her testimony. As a veterinarian present during the search of Fishman's office space, Dr. Link's firsthand observations of the searched premises are clearly permissible, and do not require rendering any expert opinion. Consequently, the defense likewise cannot preclude Dr. Link from testifying at trial.

C. Dr. Cynthia Cole, DVM

The defendants further move to preclude testimony by Dr. Cynthia Cole, DVM, PhD, who, among other professional roles, acts as a Clinical Associate Professor and Director of the University of Florida's Racing Laboratory. Ignoring (and neglecting to attach as exhibits) the two prior reports prepared by Dr. Cole and produced to the defendants well in advance of trial, on September 30, 2020, and February 17, 2021, respectively, the defendants claim that the "Government fails to provide even a cursory description of the subjects upon which it seeks to obtain opinion testimony from Dr. Cole." Def. MIL at 12. In fact, the materials produced to date make plain that Dr. Cole will, among other things, testify to her review of the defendants' own description (and lack of description, in certain cases) of the chemical components of the drugs that they peddled, and further testify regarding the effects, intended effects, and claimed effects of the performance-enhancing drugs that Fishman created and sold. *See* Exhibits F and G (disclosure letters with appended reports and CV). Her testimony is proper is every respect.

First, the subject matter of Dr. Cole's testimony will be properly directed to establishing key elements of the charged offenses and to explaining in plain terms the meaning of specialized or technical terminology deployed by Fishman in his own descriptions of his drugs. With respect to multiple, specifically identified drugs discussed in her reports, Dr. Cole will testify regarding the typical intended uses thereof, as well as the effects (including negative or dangerous effects) and intended effects of those drugs so as to demonstrate that the various substances sold by Fishman were "drugs," as defined in the FDCA. *See* 21 U.S.C. § 321(g)(1) ("The term 'drug' means (A) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) ***intended to affect*** the structure or any function of the body of man or other animals. . . .") (emphasis added)). Dr. Cole will further testify as to her personal knowledge of the bans or limitations on certain drugs by various state racing regulators, based on her extensive experience in the industry and *not* as a matter of opinion. This testimony will further establish the underlying fraudulent intent of Fishman's scheme, *i.e.*, to evade the prohibitions that apply to the various drugs that Fishman has created and distributed. Finally, Dr. Cole will provide assistance to the jury in understanding the meaning of specialized terminology deployed by Fishman in describing the intended uses, effects (including potentially dangerous effects) and constituent chemicals of Fishman's drugs, as discussed below.

Second, Dr. Cole's testimony will be based on appropriate sources of information, and draw on her deep experience and years of study. The defendants do not challenge Dr. Cole's credentials, training, or years of study as bases for deriving expert opinions; and they do not invite

a *Daubert* hearing as to any of the conclusions set forth in her reports. Rather, the defense argues that Dr. Cole's "testimony regarding the content of products manufactured and distributed by Dr. Fishman must be based upon firsthand knowledge or information obtained from qualified sources." Fishman Br. at 13. The Government does not disagree. The relevance of Dr. Cole's testimony depends on her rendering opinions regarding the drugs at issue in this case. To that end, and as her reports make clear, Dr. Cole has reviewed Fishman's own statements, labeling, and marketing material regarding the contents or purported contents of his drugs. For example, the defendants created and/or communicated to others a list of products that included both indications of the contents of the drugs and/or descriptions of their intended effects, which Dr. Cole is qualified to interpret and explain in light of her training and experience, including her experience in the racehorse industry. One specific example would be Fishman's own description of the drug "HP Bleeder Plus," contained in a document obtained from Equestology and appended to Dr. Cole's reports as one source of information from which her opinions are derived. In this description, Fishman wrote, among other things:

> A combination of a proven and test free "bleeding" (EIPH: Exercise induced pulmonary hemorrhage) and analgesic. The analgesic constituents have been published as effective and safe in peer reviewed study in global journals. Made of a combination of naturally occurring amino acids they are not easily sourced in their proper enantiomorphs.
> . . .
> HP bleeder plus contains the strongest test free vasodilators available on the market. Vasodilation is a benefit to all athletes as shown in numerous published articles for humans. Horses benefit even more as they are prone to EIPH.

Exhibit H at 1.

By way of further example, Fishman described "PSDS" in the same document, as follows:

> This product is based on the original Panacin formulation, it has 2.5 times form D-Phenylalanine then [sic] all other compounded and production versions.
> It is a mild anti-inflammatory compound and is a prominent component in wound healing. Carnosine is a major muscle buffer. In muscle tissue, phosphate and carnosine together provide approximately 90% of the buffering capacity. Intense exercise always involves an anaerobic component and thus results in significant reductions in ATP, an increase in muscle lactic acid, and an increase in tissue acidity. . . . With increasing acidity comes premature muscle fatigue, with an associated decrease in performance. Carnosine supplements provide the vital buffering capacity, as well as antioxidant activity to improve muscle function and delay fatigue. Carnosine improves cardiac contractibility, sensitizes cellular calcium channels to their activators, and protects against hydroxyl free radicals.

Id. at 2.

As the above-quoted material makes plain, testimony that will elucidate the meaning of the technical terminology, chemical references, typical intended uses, and the effects (including dangerous effects) of the drugs at issue is precisely of the sort that will "help the trier of fact to understand the evidence or . . . determine a fact in issue." Fed. R. Evid. 702. Dr. Cole's proffered opinions will be based on her unchallenged expertise drawn on experience, training, and study, and will further be based on the defendants' own claims regarding the content and intended effects of their products.

By contrast, the Government does *not* intend to elicit from Dr. Cole an opinion as to the ultimate issue of whether Fishman's conduct violated the misbranding laws, or any opinion as to Fishman's mental state – topics that are beyond the scope of expert testimony. Rather, testimony regarding the meaning of Fishman's promotional materials, the typical intended uses of certain drugs, the effects of his drugs, or the intended or purported effects as gleaned from Fishman's own words and labeling, are all issues that fall squarely within the scope of proper expert testimony. Dr. Cole's testimony should be permitted under Rule 702.

CONCLUSION

For the foregoing reasons, the Court should deny the defendants' motions *in limine* in their entirety.

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Respectfully submitted,

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